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10/551,234	07/11/2006	Philippe Tessier	6013-129US	4115

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EXAMINER	
XIE, XIAOZHEN	
ART UNIT	PAPER NUMBER
1646	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,234	TESSIER ET AL.	
	Examiner	Art Unit	
	XIAOZHEN XIE	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6 and 8-26* is/are pending in the application.

4a) Of the above claim(s) *9-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20081127*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The Information Disclosure Statement (IDS) filed 27 November 2008 has been entered. A new oath or declaration filed 11 November 2008 is acknowledged. Applicant's amendments of the specification and claims filed 27 November 2008 have been entered. Applicant's remarks filed 27 November 2008 is acknowledged.

Claims 2, 3, 5 and 7 are cancelled. Claims 1, 4, 6 and 8-26 are pending. Claims 9-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Claims 1, 4, 6 and 8 are under examination.

Oath/Declaration

The objection to the oath or declaration is withdrawn in response to Applicant's submission of a new oath on 11 November 2008 to correct the error for the filing date of PCT/CA2004/000451 (25 March 2004).

Specification

The objections to the specification for improper use of trademarks, and for typographical errors, are withdrawn in response to Applicant's amendment of the specification.

Claim Rejections Withdrawn

The rejection of claims 1-8 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in response to Applicant's

amendment of the claims to limit the S100 proteins.

The rejection of claims 1-8 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in response to Applicant's amendment of the claims to limit the S100 proteins and the patient population, and to recite "stimulating or activating...at least one immune cell type", instead of "modulating".

The rejection of claims 1-5 and 8 under 35 U.S.C. 102(b), as being anticipated by Devery et al. (J. Immunol., 1994, 152:1888-1897), is withdrawn in response to Applicant's amendment of the claims to limit the patient population to be "a human patient having neutropenia", and Devery et al. used mice in the experiments.

The rejection of claims 1-5 and 8 under 35 U.S.C. 102(e) as being anticipated by Halle et al. (US 2003/0003482 A1), is withdrawn in response to Applicant's amendment of the claims to limit the patient with neutropenia.

The rejection of claims 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over Devery et al., in view of Fidler (Cancer Res., 1985, 45:4714-4726), is withdrawn in response to Applicant's amendment of the claims to limit the patient population to be "a human patient having neutropenia".

New Ground of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halle et al. (US 2003/0003482 A1, which has a priority filing date on 17 September 2001), in view of Nicastri et al. (Int Conf AIDS. 2002 Jul 7-12; 14: abstract no. MoPeB3201), and further in view of Aboulafia (Chest, 2000, Vol. 117:1128-1145).

Halle et al. teach the use of an MRP8/MRP14 heterodimer (MRP8 also known as S100A8, and MRP14 also known as S100A9), or its individual components in combination, for treating chronic skin wounds and/or wound-healing disturbances in patients [0001]. Halle et al. teach that a variety of factors can cause disturbances of wound healing, for example, ageing, immune system diseases, nutritional deficiencies, zinc deficiency, disturbances in innervation or blood flow, diabetes, alcohol abuse and genetic defects; and severe impairments in the wound healing process can in turn lead to chronic wounds and finally to ulcers [0002]. Halle et al. teach that the term chronic skin wound normally covers very different diseases having different pathogenic backgrounds; and the most frequent representatives include diabetic ulcers, venous ulcers, arterial ulcers and decubitus ulcers [0003]. Halle et al. teach that the wound healing process includes the temporally consecutive, partially overlapping phases of coagulation, inflammation, proliferation and remodeling, and that in the inflammatory reaction, a variety of cell types, in particular neutrophilic granulocytes and monocytes, migrate into the wound and release mediators of the inflammatory reaction [0002]. Halle et al. also teaches that the routes of administration, e.g., oral, or subcutaneous administration [0059].

Halle et al. teach as set forth above. Halle et al., however, do not teach that the patients with chronic wounds have neutropenia, which is associated with cancer, anti-cancer chemotherapy or bone marrow transplant.

Nicastri et al. teach that pressure ulcers (decubitus ulcers) frequently occur among patients with advanced HIV/AIDS (see Abstract).

Aboulafia teaches that approximately 15 to 20% of men infected with HIV have Kaposi's sarcoma (pp. 1128, 1st paragraph). Aboulafia teaches that treatment of Kaposi's sarcoma in these patients can lead to significant bone marrow suppression, and that neutropenia and infection are common complications (pp. 1138, 4th paragraph in section "treatment").

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Halle et al., with those of Nicastri et al. and Aboulafia, to use MRP8/MRP14 heterodimer or its individual components in combination, for treating a chronic wound, such as decubitus ulcers, in patients with HIV/AIDS. One of ordinary skill in the art would have been motivated to do so, because Halle et al. teach that MRP8/MRP14 heterodimer or its individual components in combination is useful to provide wound healing treatment for chronic wounds, e.g., decubitus ulcers, which Nicastri et al. teach frequently occurring in HIV/AIDS patients, and Aboulafia further teaches that HIV/AIDS patients have high incidence of Kaposi's sarcoma, and the treatment commonly leads to neutropenia. Therefore, the combined teachings provide a reasonable expectation of successfully treating decubitus ulcers in these patients.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The specification as originally filed does not provide support for the invention as now claimed: "wherein said human patient is a patient having neutropenia associated with …bone marrow transplant". Applicant's amendment, filed 27 November 2008, asserts that no new matter has been added and directs support for the amended claims at various sections of the instant specification, for example, on pp. 9, line 2, "... MRP can be preferably used for immuno-suppressed patients... " and in the abstract, "...for reducing the risks of microbial infections in patients immuno-supressed." However, immuno-suppression is not the same as specifically recited "bone marrow transplantation". This is a new matter rejection.

Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.06.

Conclusion

NO CLAIM IS ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiaozhen Xie, Ph.D.
February 11, 2009

/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646